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Mr. Andrew Hackman
Senior Director of State Government Affairs
Toy Industry Association, Inc.
1115 Broadway, Suite 400
New York, NY 10010

Dear Mr. Hackman:

As requested by the Toy Industry Association (TIA), we have reviewed the materials associated with the pilot phase of the rule development process for the Reporting Rule ("Rule") of Washington state's Children's Safe Product Act (CSPA). The comments can be incorporated with others for distribution to the Washington Department of Ecology ("Ecology"), as we have discussed on previous calls. Sticking strictly to interpretation of the pilot phase of the Rule, and the associated draft reporting list of 66 chemicals, this letter report represents an evaluation and opinions regarding the process for selection and the appropriateness of inclusion of the specific chemicals on the list. Also presented are opinions placing into context the anticipated exposure to these chemicals from children's products as compared with the bases for inclusion on the list and the chemical's assumed toxicity in general. The information in this letter report is intended to assist Ecology as they progress through Phase 3 of the pilot phase. Phase 3 is intended to further refine the draft reporting list and to identify available analytical methods and propose appropriate reporting trigger levels. Our recommendations regarding appropriate reporting trigger levels will be provided as a separate submittal.

Background

Phase 1 and Phase 2 of the pilot phase process established a two-step process for development of the current draft reporting list of chemicals, a subset of which will form the final reporting list for the Reporting Rule of the Washington CSPA. Ecology, in conjunction with the Washington Department of Health (DOH), first identified the universe of potential chemicals of high concern to children (CHCC) by selecting those substances that are both high priority chemicals and that are found in humans based on evaluation of existing population studies, or which have potential exposure to children. This first step in Phase 1 was thorough and well-conceived and it resulted in reduction of the initial potential list of

thousands of substances to a preliminary reporting list of 476 chemicals. A subsequent refining process also was applied by Ecology during the Phase 1 effort that removed chemicals in a number of important categories, including the following:

- those already regulated under another framework (e.g., lead, PCBs, certain phthalates);
- those that were identified as primarily combustion byproducts (e.g., furans, PAHs);
- those that were considered to be emerging chemicals (e.g., chloroacetic acid, methyl methacrylate); and,
- those exhibiting primarily ecological toxicity (e.g., 1,2,4-trichlorobenzene, hexabromocyclododecane).

Thus, from a preliminary list of 476 substances, the final Phase 1 list contained 177 chemicals for consideration in Phase 2.

Phase 2 of the pilot phase was an attempt to focus more specifically on childhood exposure and toxicity, and included screening against a prioritization scheme developed by Dr. Catherine Karr of the University of Washington Pediatric Environmental Health Specialty Unit. Dr. Karr produced a matrix of toxicity versus exposure that ranked toxicity as “bad”, “severe” or “worst”, and exposure as “unlikely”, “possible” or “known”, depending on findings from inspection of several available databases and other sources of information available to her and to Ecology. Once the matrix and identification of appropriate databases were finalized, Ecology conducted the actual scoring of each of the 177 chemicals using that matrix. Table 1 in Attachment A presents the draft reporting list of 66 chemicals, and their final score from the toxicity/exposure matrix (e.g., “W/K” represents “worst” toxicity and “known exposure”).

All of the score sheets from the Phase 2 activities, as well as the specific screening and refining support materials from Phase 1, are available for review and download from the Ecology website (www.ecy.wa.gov/programs/swfa/rules/ruleChildPilotPhase.html), and these were reviewed in preparation of this letter report.

University of Washington’s Matrix

As noted above, Dr. Karr’s prioritization scheme was comprised of what were termed toxicity determinations and assessments of exposure potential. Both of these aspects are evaluated in depth later in this letter, but initial attention to Dr. Karr’s algorithm is appropriate here. The databases and sources of information that were identified by Dr. Karr for use in categorizing substances for toxicity generally are reliable, defensible and ultimately verifiable. However, in several instances (e.g., dimethyl phthalate, propylene glycol, phthalic anhydride, and molybdenum), substances were included on the draft reporting list due to their classification in the “Bad” level (the least restrictive level) of only one category or

only one database used. For each of these four relevant substances, the listing is based upon presence in either the ReproText database or the GHS database. Neither of these two information sources are readily searchable by the public, so it is not possible to easily confirm a listing, or to evaluate the process of selection for a substance for possible inclusion on the list. With available, reliable and peer-reviewed databases and sources such as California's Proposition 65 lists, NTPs research reports, and EU sources, for example, access and verifiability are straightforward. It is not clear that inclusion of databases such as ReproText and GHS (at least for now) adds a significant benefit to the process. Certainly they do not contribute a great deal in terms of process transparency, and the criteria for listing substances in those two databases is not uniformly well-defined or described.

In addition, it would be appropriate to include the date a database was accessed or the date of the database publication at some point on the scoring sheets. In our initial analysis, we were unable to confirm that benzoic acid was listed as a Prop 65 carcinogen, and suspected that Ecology may have had access to an unreleased or older version of the database. Ecology subsequently has acknowledged that the inclusion of benzoic acid on the draft reporting list was an error. We concur.

In either the toxicity or exposure section of the algorithm, it would be appropriate to consider whether there is available information regarding commercial beneficial use of a chemical, or demonstrated nonharmful uses. For instance, in a number of cases (e.g., methyl and propyl paraben, benzoic acid, propylene glycol, butylated hydroxyanisole) presence on the FDA GRAS (Generally Recognized as Safe) list should be considered in the complete selection process, and we suggest that those substances should be removed from the draft reporting list as it presently exists, for that reason. The majority of the GRAS list chemicals, including all of those that appear on the draft reporting list, have been evaluated by the Select Committee on GRAS Substances (SCOGS), a committee comprised of scientific experts outside of the FDA. The SCOGS reviews present conclusions for each substance on a scale of 1 to 5, with 1 being the category expressing the most support for there being no hazard to the public from common use in food. Methyl and propyl paraben, benzoic acid, and propylene glycol all are in category 1, which states the following:

There is no evidence in the available information on [substance] that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or might reasonably be expected in the future.

The SCOGS report places butylated hydroxyanisole in category 3, which concludes the following:

While no evidence in the available information on butylated hydroxyanisole demonstrates a hazard to the public when it is used at levels that are now current and in the manner now practiced, uncertainties exist requiring that additional studies be conducted.

This conclusion is consistent with Ecology's decision in several instances to postpone listing until after a Phase 3 evaluation. Table 2 shows our suggested deletions from the draft reporting list, based on unverifiable and/or limited toxicity concerns, as well as deletions based on beneficial or "generally recognized as safe" determinations for normal applications.

Toxicity - Ecology's Scoring of Chemicals

As detailed previously, the Phase 1 and Phase 2 evaluations resulted in creation of the draft reporting list of 66 substances (see Table 1). Ecology selected only those chemicals that were either W/K (worst/known), S/K (severe/known) or B/K (bad/known) with respect to the toxicity/exposure score from the Washington matrix. At the end of the Phase 3 text description (www.ecy.wa.gov/programs/swfa/rules/pdf/p3text.pdf), Ecology notes that, as a first step in Phase 3, ethanol and quartz were removed from further consideration, methyl mercury was shifted to the "mercury and mercury compounds" entry, and two arsenic compounds were shifted to the "arsenic and arsenic compounds" entry. Thus, the draft reporting list ultimately contained 61 substances as a starting point. It is apparent from review of the supporting tables and score sheets for Phase 2 that the following five substances were promoted to the reporting list, even though they did not fit the stated objective of only selecting chemicals having a known ("K") potential for exposure to children, combined with worst, severe or bad toxicity score:

- tetrabromobisphenol A ("Phase 3/P"; "P" is for possible exposure, but no tox conclusion in Phase 2, shifted to Phase 3 for tox determination);
- hexabromocyclododecane ("Phase 3/K"; "K" is for known exposure, but no tox conclusion in Phase 2, shifted to Phase 3 for tox determination);
- hexachlorobutadiene ("B/P");
- hexachlorobenzene ("W/P"); and,
- pentachlorobenzene ("W/P").

No description of the process by which these five chemicals were selected and included was found in the Ecology supporting documentation. We recommend for consistency that these five substances be held out for further review during Phase 3, as appears to be the intent for at least the first two, based on their toxicity score of "Phase 3".

Toxicity – Endocrine Disruption

The evaluation of substances to determine their endocrine disruption potential is a field of science that is in relative infancy compared with other toxicological sciences. At this point, there is strong evidence for certain chemical exposures being associated with adverse developmental and reproductive effects in fish and wildlife. However, such a relationship to human diseases of the endocrine system is poorly understood and scientifically controversial. For example, the ability of some substances to cause endocrine effects at high levels of exposure

often does not translate to a similar character of effects at very low doses. Through inclusion of only the EU endocrine classification system on the toxicity/exposure matrix, Ecology acknowledges that the European Union approach to evaluating potential endocrine disruptors represents the present “state of the science”. It should further be acknowledged that the EU does not regulate chemicals based solely on their endocrine disruption status. Rather, they consider all potential endocrine disruptors, whether identified preliminarily as Category 1, 2 or 3, to be substances requiring further study on a case-by-case basis prior to inclusion, for example, as outlined in the REACH (Registration, Evaluation, and Authorization of Chemicals) guidelines.

The draft reporting list includes 11 substances that are present solely due to their classification as potential endocrine disruptors. In addition, the list contains two substances (diethyl phthalate and octamethylcyclotetrasiloxane) that are listed as potential endocrine disruptors, and that are listed in only one other toxicity category. We recommend that these 13 substances be removed from the draft reporting list and that they undergo further review during Phase 3, or once more reliable assessment techniques or consensus conclusions are available for evaluating endocrine disruption potential at low levels of exposure (see Table 3; note that methyl and propyl paraben do not appear on Table 3 because they were recommended for removal due to presence on the GRAS list; see Table 2).

Toxicity – Carcinogenicity

In 2005, USEPA released its *Supplemental Guidance for Assessing Cancer Susceptibility from Early-life Exposure to Carcinogens*. The document suggests that childhood exposure to certain specific types of substances may result in greater cancer risk over a lifetime than if exposures occur later in life. The guidance is quite specific to carcinogens exhibiting a mutagenic mode of action (e.g., vinyl chloride) and not necessarily those acting via a non-mutagenic mode (e.g., dieldrin, perchloroethylene). Chemicals on the draft reporting list that are identified solely or primarily on the basis of potential carcinogenicity (e.g., 2-aminotoluene, estragole) should be evaluated to more conclusively assess their specific carcinogenic mode of action and whether they truly represent an increased concern for childhood exposure by the USEPA criteria. USEPA has developed a *Framework for Determining a Mutagenic Mode of Action for Carcinogenicity* just for such purposes.

In the specific case of estragole, a naturally occurring plant oil, it shows up on only one of the six cancer databases used in the matrix, and that single entry is the Prop 65 list of potential carcinogens. It does not appear on any of the other five carcinogenicity lists or any of the reproductive or developmental toxicity lists. Ecology, in their Phase 2 documentation materials, notes that Prop 65 does not use the same rigorous methods as the other databases, and, thus, they assign only the “severe” classification to Prop 65 carcinogens rather than the “worst” level. For that reason, we recommend the removal of estragole from the draft reporting list.

In summary, Table 3 in Attachment A presents our suggested list of chemicals that should be removed from the draft reporting list based either on their classification predominantly as endocrine disruptors, based on insufficient evidence for inclusion, or based on limited support for potential carcinogenicity.

Exposure Potential

Because Ecology elected to include only those substances that scored in the “known” category for exposure, and because Phase 3 is slated to further evaluate actual exposure potential for each entry, this report primarily addresses toxicity concerns. However, the following important exposure considerations warrant attention at this stage in the process as well:

Inhalation exposure – although significant inhalation exposure to many of the substances on the draft reporting list may indeed occur in occupational and even certain unusual environmental scenarios, significant inhalation exposure to children while playing with toys or other products is highly unlikely under reasonable circumstances. During Phase 3, it is recommended that close scrutiny be applied to those substances for which inhalation is the primary or only reasonably expected route of exposure of concern (e.g., acetaldehyde, formaldehyde).

Accessibility – the Phase 1 and Phase 2 evaluations of exposure looked primarily at the likelihood for the presence of a substance in children’s products, and did not assess the possibility that a substance may occur only in inaccessible parts of a toy. This possibility must be left open for potential delisting of a chemical in the future, perhaps prior to (e.g., for new proposed additions to the list), or in addition to, the more detailed evaluation envisioned by Ecology for Phase 3 (e.g., with respect to the existing list).

In summary, we recommend removal of the following substances from the CPSA draft reporting list, for the reasons noted:

Antimony & compounds	Database Concerns
Benzoic acid	GRAS
Butylated hydroxyanisole	GRAS
Diethyl ether	Database Concerns
Dimethyl phthalate	Database Concerns
Methyl paraben	GRAS
Molybdenum & compounds	Database Concerns
Phthalic anhydride	Database Concerns
Propyl paraben	GRAS
Propylene glycol	GRAS
2-ethyl-hexyl-4-methoxycinnamate	Endocrine Disruptor
4-Nonylphenol; 4-NP	Endocrine Disruptor
4-tert-Octylphenol	Endocrine Disruptor
Benzophenone-2 (Bp-2)	Endocrine Disruptor
Butyl paraben	Endocrine Disruptor
Diethyl phthalate	Endocrine Disruptor
Estragole	Insufficient Evidence
Ethyl paraben	Endocrine Disruptor
Hexabromocyclododecane	Insufficient Evidence
Hexachlorobenzene	Insufficient Evidence
Hexachlorobutadiene	Insufficient Evidence
Mono 2 ethyl hexylphthalate	Endocrine Disruptor
Octamethylcyclotetrasiloxane	Endocrine Disruptor
p-Hydroxybenzoic acid	Endocrine Disruptor
Pentachlorobenzene	Endocrine Disruptor
Tetrabromobisphenol A	Insufficient Evidence

Please call Doug Covert or me at (850) 681-6894 when you have had an opportunity to review this information, so we can answer any questions or provide clarification as appropriate.

Sincerely,



Christopher M. Teaf, PhD
President & Director of Toxicology

Attachment (1)

ATTACHMENT A

Tables

Table 1

Basis for Inclusion and Final Determinations for Draft Reporting List Substances

		WA DoE Toxicity Basis for Inclusion on the Draft Reporting List														Final	Final
Substance	CAS #	Prop 65 repro	NTP repro	EU repro	GHS repro	ReproText	LOAEL or RTECS	EU endo	IARC	NTP carc	IRIS carc	EU carc	GHS carc	Prop 65 carc	Toxicity Score	Exposure Score	
Hexabromocyclododecane	25637-99-4						severe								Phase 3	Known	
Tetrabromobisphenol A	79-94-7						severe								Phase 3	Possible	
Dimethyl phthalate	131-11-3					bad									Bad	Known	
Hexachlorobutadiene	87-68-3				bad		worst				bad		bad		Bad	Possible	
Molybdenum & molybdenum compounds	7439-98-7					bad									Bad	Known	
Phthalic anhydride	85-44-9				bad										Bad	Known	
Propylene glycol	57-55-6		No			bad									Bad	Known	
1,1,2,2-Tetrachloroethane	79-34-5				bad						bad			severe	Severe	Known	
1,4-Dioxane	123-91-1								bad	severe	severe		bad	severe	Severe	Known	
2-Ethylhexanoic Acid	149-57-5		severe	bad	severe		severe								Severe	Known	
2,2',3,3',4,4',5,5',6,6'-Decabromodiphenyl ether; BDE-209	1163-19-5				bad		severe	severe			severe				Severe	Known	
2,4-Diaminotoluene	95-80-7			bad	bad		severe		bad	severe		severe	bad	severe	Severe	Known	
Acetaldehyde	75-07-0					severe			bad	severe	severe		bad	severe	Severe	Known	
Acrylonitrile	107-13-1				bad	severe	worst		bad	severe	severe	severe	bad	severe	Severe	Known	
Antimony & Antimony compounds	7440-36-0					severe									Severe	Known	
Benzoic acid	65-85-0													severe	Severe	Known	
C.I. Solvent Yellow 14	842-07-9			bad										severe	Severe	Known	
Cobalt & Cobalt compounds	7440-48-4				bad	severe			bad				bad	severe	Severe	Known	
Diethyl ether	60-29-7				bad	severe									Severe	Known	
Estragole	140-67-0													severe	Severe	Known	
Ethylbenzene	100-41-4				severe	bad	severe		bad				bad	severe	Severe	Known	
Ethylene glycol	107-21-1		severe		severe	severe									Severe	Known	
Methyl ethyl ketone	78-93-3					severe	bad								Severe	Known	
n-Butanol	71-36-3					severe	bad								Severe	Known	
N-Nitrosodimethylamine	62-75-9				bad		worst		severe	severe	severe	severe	severe	severe	Severe	Known	
N-Nitrosodiphenylamine	86-30-6										severe		bad	severe	Severe	Known	
para-Chloroaniline	106-47-8				bad				bad			severe		severe	Severe	Known	
Perchloroethylene	127-18-4				bad	severe	severe	severe	severe	severe			severe	severe	Severe	Known	
perfluorooctanyl sulphonic acid and its salts; PFOS	1763-23-1			severe			worst								Severe	Known	
Phenol	108-95-2			bad	severe	severe									Severe	Known	
Tris(2-chloroethyl) phosphate	115-96-8			severe	severe									severe	Severe	Known	
2-Aminotoluene	95-53-4								worst	severe		severe	severe	severe	Worst	Known	
2-ethyl-hexyl-4-methoxycinnamate	5466-77-3							worst				severe	severe		Worst	Known	
2-Methoxyethanol	109-86-4	worst		severe	severe	severe									Worst	Known	
3,3'-Dimethylbenzidine and Dyes Metabolized to 3,3'-Dimethylbenzidine	119-93-7	worst							bad	severe		severe	bad	severe	Worst	Known	
4-Nonylphenol; 4-NP	104-40-5							worst							Worst	Known	
4-tert-Octylphenol; 1,1,3,3-Tetramethyl-4-butylphenol	140-66-9							worst							Worst	Known	
Aniline	62-53-3			severe	bad	worst					severe		bad	severe	Worst	Known	
Arsenic & Arsenic compounds	7440-38-2	worst			worst		worst		worst	worst	worst		worst		Worst	Known	
Benzene	71-43-2	worst		severe	bad	severe	severe		worst	worst	worst	worst	worst	severe	Worst	Known	
Benzophenone-2 (Bp-2), 2,2',4,4'-tetrahydroxybenzophenone	131-55-5							worst							Worst	Known	
Beryllium & Beryllium compounds	7440-41-7	worst				severe									Worst	Known	
Bisphenol A	80-05-7		severe	bad	bad		worst	worst							Worst	Known	
Butyl paraben	94-26-8							worst							Worst	Known	
Butylated hydroxyanisole	25013-16-5						bad	worst	bad	severe				severe	Worst	Known	
Carbon disulfide	75-15-0	worst		bad	severe	worst	worst								Worst	Known	
Di-n-Hexyl Phthalate	84-75-3	worst	severe		worst			severe							Worst	Known	
Diethyl phthalate	84-66-2						worst	worst							Worst	Known	
Ethyl paraben	120-47-8							worst							Worst	Known	
Ethylene glycol monoethyl ester	110-80-5	worst		severe	severe	severe	worst								Worst	Known	
Formaldehyde	50-00-0				bad	severe	severe		worst	severe	severe	severe	bad	severe	Worst	Known	
Hexachlorobenzene	118-74-1	worst			worst		severe	worst	bad	severe	severe	severe	bad	severe	Worst	Possible	
Mercury & mercury compounds	7439-97-6	worst		severe	worst	severe			bad		bad				Worst	Known	
Methyl paraben	99-76-3							worst							Worst	Known	
Methylene chloride	75-09-2					worst	bad		bad	severe				severe	Worst	Known	
Mono 2 ethyl hexylphthalate; MEHP	4376-20-9							worst							Worst	Known	
N-Methylpyrrolidone	872-50-4	worst		severe	bad	severe									Worst	Known	
Nonylphenol	25154-52-3			bad	severe		severe	worst							Worst	Known	
Octamethylcyclotetrasiloxane	556-67-2			bad				worst							Worst	Known	
p-Hydroxybenzoic acid	99-76-7							worst							Worst	Known	
Pentachlorobenzene	608-93-5							worst							Worst	Possible	
Phenol, 4-octyl-	1806-26-4				bad		worst								Worst	Known	
Propyl paraben	94-13-3							worst							Worst	Known	
Styrene	100-42-5		No		severe	severe	bad								Worst	Known	
Toluene	108-88-3	worst		bad	worst	worst			bad						Worst	Known	
Vinyl chloride	75-01-4				bad	severe	severe		worst	worst	worst	worst	worst	severe	Worst	Known	

Table 2

**Subset of Substances Proposed for Removal
based on Beneficial Use Designation or Database Concerns**

Substance	CAS#	Reason for Proposed Removal
Antimony & antimony compounds	7440-36-0	Database Concerns
Benzoic acid	65-85-0	GRAS
Butylated hydroxyanisole	25013-16-5	GRAS
Diethyl ether	60-29-7	Database Concerns
Dimethyl phthalate	131-11-3	Database Concerns
Methyl paraben	99-76-3	GRAS
Molybdenum & molybdenum compounds	7439-98-7	Database Concerns
Phthalic anhydride	85-44-9	Database Concerns
Propyl paraben	94-13-3	GRAS
Propylene glycol	57-55-6	GRAS

GRAS indicates that the substance is present on the US FDA Generally Recognized as Safe list of food additives.

Database Concerns indicates that the substance is only identified on one or both of the GHS or ReproText databases, which are either in the development stage or are not readily verifiable.

Table 3

**Subset of Substances Proposed for Removal
based on Insufficient Evidence or Endocrine Disruption**

Substance	CAS#	Reason for Proposed Removal
2-ethyl-hexyl-4-methoxycinnamate	5466-77-3	Endocrine Disruptor
4-Nonylphenol; 4-NP	104-40-5	Endocrine Disruptor
4-tert-Octylphenol; 1,1,3,3-Tetramethyl-4-butylphenol	140-66-9	Endocrine Disruptor
Benzophenone-2 (Bp-2); 2,2',4,4'-tetrahydroxybenzophenone	131-55-5	Endocrine Disruptor
Butyl paraben	94-26-8	Endocrine Disruptor
Diethyl phthalate	84-66-2	Endocrine Disruptor
Estragole	140-67-0	Insufficient Evidence
Ethyl paraben	120-47-8	Endocrine Disruptor
Hexabromocyclododecane *	25637-99-4	Insufficient Evidence
Hexachlorobenzene *	118-74-1	Insufficient Evidence
Hexachlorobutadiene *	87-68-3	Insufficient Evidence
Mono 2 ethyl hexylphthalate; MEHP	4376-20-9	Endocrine Disruptor
Octamethylcyclotetrasiloxane	556-67-2	Endocrine Disruptor
p-Hydroxybenzoic acid	99-76-7	Endocrine Disruptor
Pentachlorobenzene *	608-93-5	Endocrine Disruptor
Tetrabromobisphenol A *	79-94-7	Insufficient Evidence

Endocrine Disruptor indicates that the substance is listed on the draft reporting list predominantly due to its potential endocrine disruption capability.

Insufficient Evidence indicates that the substance is listed on the draft reporting list based on inclusion on only one or two databases.

* The noted substances appear to have been promoted to the list arbitrarily following early Phase 3 refinements. They are not classified as "known" for exposure potential.